

REMARKS

Claims 1 and 4-33 were pending. The applicants present claims 1 and 4-33 for examination in light of the following remarks.

Claims 1 and 4-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,368,045 ("Clement") in view of U.S. Pat. No. 5,197,484 ("Kornberg"), and further in view of U.S. Pat. No. 5,467,684 ("Sher"), in combination or in further combination with U.S. Pat. No. 5,921,943 ("Kass"); U.S. Pat. No. 5,394,887 ("Haaga"); U.S. Pat. No. 6, 331,166 ("Burbank"); or U.S. Pat. No. 5,649,547 ("Ritchart").

Claim 1 recites

a stylet block attached to a proximal end of the stylet and mounted inside the housing, the stylet block comprising:

a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and
a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet.

Claim 15 recites

moving a stylet and a stylet block from a first position to a second position, the stylet block having an axially moveable first part and a second part attached to the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet;

Claim 22 recites

a stylet block, the stylet block attached to a proximal end of the stylet and mounted inside the housing, the stylet block comprising:

a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and
a second part attached to the proximal end of the stylet, the second part being rotatably engaged and in contact with the first part and being able to rotate relative to an axis of the stylet.

The cited references, alone or in combination, do not describe or make obvious medical instruments or methods of using medical instruments with the stylet blocks as claimed by the applicants.

Clement does not describe a stylet block as claimed by the applicants. The office action acknowledges that

Clement et al. disclose an system, as described above, that fails to teach a stylet configured to rotate when moved from the first retracted position to the first extended position.¹

Thus, Clement does not disclose a stylet block with, for example, “a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet” (claim 1). Neither Kornberg nor Sher remedy this deficiency of Clement.

The office action asserts that

it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Clement et al. as modified by Kornberg and Sher above with a driving mechanism such that linear displacement of the stylet causes rotational motion of the stylet as claimed in order to automatically simultaneously rotate and advance the stylet through the tissue.²

Whether or not this assertion is correct, the applicants have claimed, for example, a stylet block comprising: “a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet” (claim 1) rather than “a driving mechanism such that linear displacement of the stylet causes rotational motion of the stylet as claimed in order to automatically simultaneously rotate and advance the stylet through the tissue.”³ Thus, the cited references have not been shown to describe all the features claimed of the devices and methods claimed by the applicants and do not support a prima facie case of obviousness.

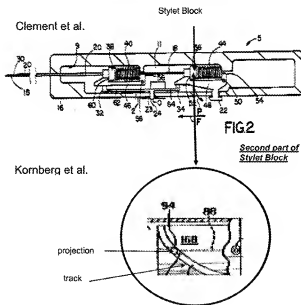
Moreover, the proposed combination of references would not result in a medical device as claimed by the applicants as neither Kornberg nor Sher describe a medical device with a stylet block with “a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet” (claim 1). As best understood by the applicants (based on the annotated figures in the office action reproduced below), the examiner is asserting that the projection 94

¹ Office action dated May 21, 2009, page 4.

² Office action dated May 21, 2009, pages 4-5.

³ Office action dated May 21, 2009, page 5.

and track 158 described by Kornberg as being used to drive the cannula forward are equivalent to the second part of the stylet block as recited by the applicant's claims. However, the mechanism described by Kornberg has not been shown to have "a first part inside the housing, the first part being moveable between a third extended position and a third retracted position" with which the second part is rotatably engaged. Thus, Kornberg does not describe a stylet block as claimed by the applicants.



The examiner "submits that Clement et al. fully teach a stylet block and Kornberg et al. fully teach a second part comprising a projection and track."⁴ However, if the device described by Clement were modified to use the projection / track mechanism described by Kornberg, Clement's device would no longer require its original stylet block and, thus, the modified device would not include a stylet block comprising: a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet.

Sher also does not describe a stylet block with a first part moveable between an extended position and a retracted position; and a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis

⁴ Office action dated May 21, 2009, page 10.

of the stylet. Rather, Sher discloses a piston 3 with a wave-shaped groove 8 defined in its outer surface which engages guide members 9 extending inward from a housing or, in an alternate embodiment, a piston 3 with guide members 9 extending outward from the piston to a wave-shaped groove defined in the housing.⁵

In addition, the proposed motivation for combining the references lacks the rational underpinning necessary to sustain an obviousness rejection.⁶ The office action makes the conclusory statement that "it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Clement et al. with a simultaneously rotating and forwardly driven cannula mechanism as taught by Kornberg et al. in order to automatically rotate the cannula as it penetrates tissue so as to facilitate tissue penetration."⁷ However, the examiner has not provided any reason that a person of ordinary skill in the art who was aware of Clement and Kornberg and who desired a biopsy device with an automatically rotating cannula would modify the device described by Clement rather than just using the device described by Kornberg. Further, the applicants submit that, in the absence of a detailed analysis of Appellants' disclosure, a person of ordinary skill in the art with Kornberg's biopsy device in hand would have no reason to investigate the field of piston-driven cutting devices and drills to uncover Sher. Thus, only impermissible hindsight reconstruction would provide a basis for the proposed combination of references. However, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.⁸ For at least these reasons, the examiner's articulated reason for modifying Clement and proposed combination of references lacks the rational underpinning necessary to support the legal conclusion of obviousness.⁹

⁵ Sher, col. 3, lines 29-64 and col. 5, lines 56-60.

⁶ See *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727 at 1740 (2007) citing *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" – emphasis added).

⁷ Office action dated May 21, 2009, pages 4-5.

⁸ *In re Fine*, 837 F.2d at 1075, 5 USPQ2d at 1600. See also *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct. 1727 at 1742 ("A fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.")

⁹ See *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727 at 1740 (2007) citing *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements;

For at least these reasons, none of the cited references has been shown to disclose or make obvious a stylet block with a first part moveable between an extended position and a retracted position; and a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet. Accordingly, Clement, Kornberg, and Sher, in combination or in further view of Kass; Haaga; Burbank; or Ritchart do not provide the basis for a prima facie case of obviousness of the pending claims.

All of the dependent claims are patentable for at least similar reasons as those for the claims on which they depend are patentable.

Canceled claims, if any, have been canceled without prejudice or disclaimer.

Any circumstance in which the applicants have (a) addressed certain comments of the examiner does not mean that the applicants concede other comments of the examiner, (b) made arguments for the patentability of some claims does not mean that there are not other good reasons for patentability of those claims and other claims, or (c) amended or canceled a claim does not mean that the applicants concede any of the examiner's positions with respect to that claim or other claims.

No fees are believed to be due. Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 01194-0824001.

Respectfully submitted,

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